UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

SEKISUI AMERICA CORPORATION and SEKISUI MEDICAL CO. LTD., Plaintiffs, v. RICHARD HART and MARIE LOUISE TRUDEL-HART, Defendants.	12 Civ. 3479 (SAS) (FM)
RICHARD HART and MARIE LOUISE TRUDEL-HART, Plaintiffs, v. SEKISUI AMERICA CORPORATION and SEKISUI MEDICAL CO. LTD., Defendants.	12 Civ. 3560 (SAS) (FM)

DECLARATION OF THOMAS D. BECZE IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* TO EXCLUDE PORTIONS OF THE EXPERT REPORT AND TESTIMONY OF THOMAS D. BECZE

1. I am an expert in quality assurance and regulatory affairs for the medical device and pharmaceutical industries with over 33 years of experience. I was retained by Defendants Richard Hart and Marie Louise Trudel-Hart (the "Harts") to rebut the expert reports of Plaintiffs' FDA compliance expert, Carrie M. Kuehn, and Plaintiffs' 510(k) expert, Timothy A. Ulatowski.

2. I understand Plaintiffs have moved *in limine* to exclude portions of my Expert Report, submitted on August 5, 2013. I submit this Declaration in support of the Harts' Opposition to Plaintiffs' Motion *In Limine*.

3. I understand Plaintiffs have asserted that I lack sufficient experience with 510(k) submissions to opine about Mr. Ulatowski's conclusion that American Diagnostica, Inc.'s 2009 FEMTELLE 510(k) was destined to fail. Contrary to Plaintiffs' contention, I have substantial experience regarding 510(k) submissions. As set forth in my *curriculum vitae* attached to my expert report, I have composed, assembled, and submitted to the FDA seventy-four "IDEs, PMAs, and 510(k)s." I have served as an expert witness in "Regulatory Affairs (CDRH)." "Regulatory Affairs (CDRH)" encompasses 510(k) submissions.

4. A 510(k) is a premarket submission to the FDA that seeks approval to market a medical device by showing the device is substantially equivalent to a medical device that has already been cleared by the FDA. IDEs and PMAs are other types of submissions related to medical devices.

5. Despite the information in my *curriculum vitae*, Plaintiffs did not ask me a single question about my experience composing, assembling, and submitting 510(k) notifications. To assist the Court in reviewing my qualifications, I provide the following additional information.

6. Of the seventy-four medical device premarket submissions referenced in my *curriculum vitae*, approximately sixty-five are 510(k)s I have composed, assembled and submitted to the FDA on behalf of clients and for which I have advised clients through the entire life cycle of the 510(k) (from submission to clearance).

7. All 510(k)s are submitted to the FDA's Center for Devices and Radiological Health ("CDRH"), which oversees premarket submissions for medical devices. The CDRH includes the Office of Device Evaluation ("ODE"), the Office of In Vitro Diagnostics and Radiological Health ("OIVD"), and the Office of Compliance, among others. The ODE and OIVD are responsible for reviewing 510(k) submissions.

8. For each 510(k) I worked on, I interacted extensively with FDA personnel in at least four divisions in the ODE. I have responded to requests for additional information and questions from ODE personnel regarding the 510(k) submissions. I have had numerous communications with senior staff in the CDRH regarding the submissions and compliance.

9. All but one of the 510(k)s I composed and submitted were cleared by the FDA. One was withdrawn at the client's request.

10. I also understand Plaintiffs have asserted that my opinion is not based on sufficient facts or data because I did not review the 2009 FEMTELLE 510(k). As I testified during deposition, I did not need to review the 510(k) to rebut Mr. Ulatowski's opinion that it was "destined to fail."

11. Mr. Ulatowski cites the 2009 FEMTELLE 510(k) only twice in his report, once in the appendix of documents reviewed and once in a footnote to support his statement, in the chronology section of his report, that the 2009 510(k) was submitted to the FDA. In opining that it was "destined to fail," Mr. Ulatowski does not say anything about, or even cite, the contents or composition of the 510(k). Instead, to render his opinion, Mr. Ulatowski discusses and relies exclusively on internal ADI correspondence and correspondence between ADI and the FDA. To rebut Mr. Ulatowski's opinion, I reviewed and relied on this same correspondence.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: November 15, 2013
New York, New York

Thomas D. Becze